TABLE OF CONTENTS

FOR ENVIRONMENTAL RESTORATION MANAGEMENT

QUALITY ASSURANCE PROGRAM DESCRIPTION

DOCUMENT MODIFICATION REQUEST (DMR)

Refer to 1-A01-PPG-001 for Processing Instructions.
Print or **Type** All Information (Except Signatures)

1. Date 9/23/94

25. DMR. No. 94-DMR-ERM-0127 CBJ 10/24/94

2. Existing Document Number/Revision: ER-MP-QAPD, R1

3. New Document Number or Document Number if it is to be changed with this Revision

4. Originator's Name/Phone/Page/Location: Mark Castagneri/8582/080-439

5. Document Title: Quality Assurance Program Description for ERM

6. Document Type ❑ Procedure ☒ Other Program Description

7. Document Modification Type (Check only one) ❑ New ❑ Revision ❑ Intent Change ☒ Nonintent Change ❑ Editorial Correction ❑ Cancellation

8. Item	9. Page	10. Step	11. Proposed Modifications
1	1 of 12	Sec. 6.0	First paragraph after the first sentence add: "This section implements all DOE requirements for software system development, control, testing, and documentation, including those requirements provided in the Price-Anderson Act, 10CFR830.120 (Quality Assurance).
2	5 of 12	Sec. 6.2	Replace the first sentence of the second paragraph with: "This section applies to software that routinely supports the ERM mission. Typical examples are RFI/RI reports, periodic environmental monitoring or status reports, and database extracts and reports providing routine geotechnical information. Limited use software and systems providing calculations or data reduction for scientific investigations are excluded from the requirements of this section. Control and documentation of electronic calculations and other limited-use programs are addressed in Section 5.3, "Control of Measurements and Data Acquisition Process"."
3	5 of 12	Sec. 6.2	Add the following sentence at the end of the second paragraph: "The methods of requirements application and definitions of software specifically excluded from the requirements of this section are defined in the Environmental Restoration Management Software Management Plan (ERM SMP), 2-G24-ER-ADM-19.01."
4	5 and 6 of 12	Sec. 6.2	Delete the third paragraph and bullets that follow and the fourth paragraph.
5	6 of 12	Sec. 6.2.1	First paragraph, first sentence, "The development and...orderly manner." delete parenthesis and enclosed reference and add the following sentence: "All software development routinely supporting ERM activities shall be conducted according to requirements in the ERM Software Management Plant (SMP), 2-G24-ER-ADM-19.01."
6	7 of 12	Sec. 6.2.1	Under subheader "Testing", first paragraph first sentence "...by executing test cases." delete parenthesis and enclosed reference.
7	7 of 12	Sec. 6.2.1	Under subheader "Testing", first paragraph, last sentence, "The code shall not be used until..." replace remainder of sentence with: "a successful test is performed, documented, and approved."
8	8 of 12	Sec. 6.2.1	Under subheader "Installation and Checkout", first paragraph, third sentence, "...software shall be controlled in accordance with...", replace remainder of sentence with: "the ERM SMP, 2-G24-ER-ADM-19.01."
9	9 of 12	Sec. 6.2.2	Delete last sentence of the paragraph.
10	9 of 12	Sec. 6.2.4	First paragraph, last sentence, replace parenthesis reference with: "(see 2-G24-ER-ADM-19.01)."
11	9 of 12	Sec. 6.2.4	Subheader "Software Verification" delete entire subheader, title, and following sentence with bullets.
12	10 of 12	Sec. 6.2.5	Under subheader "Configuration Identification" last sentence "The ERM configuration control program is described in..." replace remainder of sentence with: "2-G24-ER-ADM-19.01."
13	10 of 12	Sec. 6.2.5	Under subheader "Configuration Change Control" replace parenthesis reference with: "(see 2-G24-ER-ADM-19.01)."
14	11 of 12	Sec. 6.2.6	Second sentence add: "...as specified:" to the end of the sentence and replace bullets as follows: • Software requirements • Software design • Software change control/revision releases • Software test plans and results • User's Manual, Training Guide, and User Training Rosters.

12. Justification (Reason for Modification, EJO#, TP#, etc.)

To coordinate ERM requirements for software development QA/QC, making the QAPD and the new Software Management Plan (ADM 19.01) consistent.

If modification is for a new procedure or a revision, list concurring disciplines in Block 13, and enter N/A in Blocks 14 and 15. If modification is for any type of change or a cancellation, organizations are listed in Block 13, then Concurror prints, and signs in Block 14, and dates in Block 15.

13. Organization	14. Print and Sign (if applicable)	15. Date (if applicable)
QS	Steve Luker [signature]	9-30-94
ED	Laura Tyler [signature]	10-5-94

16. Originator's Supervisor (print/sign/date): Chris Daily [signature] 10/3/94

17. Assigned SME/Phone/Page/Location: Mark Brooks/8516/080

18. Cost Center

19. Charge Number

20. Requested Completion Date

21. Effective Date 11/3/94

22. Accelerated Review? Yes ❑ No ☒

23. ORC Review: N/A

24. Responsible Manager (print, sign, date): Mark Brooks [signature] 9/29/94

REVIEWED FOR CLASSIFICATION/UCNI
BY NA
DATE NA

TITLE: DESIGN

Approved By:

Signature on file 11/27/94
Associate General Manager
Environmental Restoration Management

Signature of file 11/02/94
Director
Environmental Quality and Records Management

Effective Date: 11-03-94

TABLE OF CONTENTS

LIST OF EFFECTIVE PAGES

Page	Effective Date	Change Number
1-2	10/ /94	94-DMR-ERM-0127
5-11	10/ /94	94-DMR-ERM-0127

reviewers shall be considered QA records and shall be controlled in accordance with Section 4.2, QA Records, of this QAPD.

6.2 Software Quality Assurance

This subsection specifically applies to computer software used by ERM and subcontractor personnel to generate or manage data that are reported to federal, state, or local regulatory agencies.

94-DME-ERM-0127

This section applies to software that routinely supports the ERM mission. Typical examples are RFI/RI reports, periodic environmental monitoring or status reports, and database extracts and reports providing routine geotechnical information. Limited use software and systems providing calculations or data reduction for scientific investigations are excluded from the requirements of this section. Control and documentation of electronic calculations and other limited-use programs are addressed in Section 5.3, "Control of Measurement and Data Acquisition Process". The extent to which the requirements of this section apply shall be related to the nature, complexity, and importance of the software application. The requirements of Sections 6.2.5, 6.2.8, and the applicable portions of 6.2.6 apply to data files that provide manufacturing, measuring, inspection, test, or acceptance parameters for a product or process. The methods of requirements application and definitions of software specifically excluded from the requirements of this section are defined in Environmental Restoration Management Software Management Plan (ERM SMP), 2-G24-ER-ADM-19.01.

94-DME-ERM-0127

Computer software shall be developed, controlled, revised, and maintained to reduce the likelihood of defects entering executable codes during development, modification, and operation, and to ensure that the end product satisfies the requirements of its intended application. Software shall be verified, validated, and documented consistent with its nature, complexity, and intended application.

6.2.1 Software Development

94-DME-EEM-0127

Computer software, including computer programs and computer models, for use in ER MSA Project activities shall be developed and revised in a traceable, planned, and orderly manner. All software development routinely supporting ERM activities shall be conducted according to requirements in the ERM Software Management Plan (SMP), 2-G24-ER-ADM-19.01. The number of phases and relative emphasis placed on each phase of software development will depend on the nature and complexity of the software. Software development may be performed in an iterative or sequential manner.

Software requirements relating to functionality, performance, design constraints, attributes, and external interfaces shall be specified, documented, and reviewed. The requirements shall define the response of the software to input data and shall provide the detail and information necessary to design and test the software. The requirements shall be approved by the appropriate level of management as described in approved written procedures.

Design

Software design shall be developed based on software requirements. The design will be documented, reviewed, and approved in accordance with 2-G24-ER-ADM-19.01. The

design shall specify the overall structure (control and data flow) and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures).

Implementation

Software design shall be translated into a programming language, and the software shall be analyzed to identify and correct errors. Software verification shall consist of examination of source code listings to ensure adherence to internal coding standards and conventions.

94-DME-ERM-0127

Testing

94-DME-ERM-0127

Testing of the software design shall be conducted prior to acceptance of the design by executing test cases. Failure to successfully execute the test cases shall result in a review of the design to determine if modifications to the requirements, design, implementation, or test plans and test cases are required. The code shall not be used until a successful test is performed, documented and approved.

Testing of the software design consists of validating the code to ensure adherence to the requirements and to ensure that the software produces correct results for the test case. Evaluation of the technical adequacy of the software design consists of comparing the test case results with alternative methods, including:

- Analysis without computer assistance
- Other validated computer programs
- Experiments and tests
- Standard problems with known solutions
- Confirmed published data and correlations

Test results shall be documented and verified by a responsible authority. Verification of test records include:

- Computer program/hardware tests
- Test equipment and calibration
- Date of test
- Name of tester
- Simulation models used
- Test problems
- Results and acceptability
- Actions taken in connection with deviations

Installation and Checkout

After the software becomes part of a system by incorporating applicable software components, hardware, and data, and by verifying that all system components have been included, the software installation phase shall be performed. The software installation phase shall consist of installation, integration, checkout, and documentation of the approval of the software for operation use. At this stage, software shall be controlled in accordance with the ERM SMP 2-G24-ER-ADM-19.01. Pre developed test problems shall be run whenever the software is installed on a different computer or whenever significant hardware changes are made.

94-DME-ERM-0127

6.2.2 Commercial Software

Where commercial off-the-shelf software is used, available documentation from the software supplier shall be obtained in order to evaluate the software's adequacy to meet its intended application. Examples of this type of software include mathematical/numerical data reduction software, models, data management software, and computer language compilers. A source code is generally not available, and controls are limited to the unique version identification

94-DMR-ERM-0127

and user-related manuals for such software.

6.2.3 Acquired Software

Acquired software is considered noncommercial software obtained from organizations outside ERM. Acquired software requires documented validation to demonstrate that it performs its stated capabilities and functions. ERM or subcontractor personnel shall validate the software in accordance with written test plans (see 2-G25-ER-ADM-19.02). The specific form of the test plan is determined by the tester, but the software options to be tested, the data to be used as input, the expected results, and the acceptance criteria must be identified.

6.2.4 Software Verification and Model Validation

94-DMR-ERM-0127

Software verification and validation shall be planned and performed for each system configuration that may impact the system to ensure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that, either by itself or in combination with other functions, can degrade the entire system (see 2-G24-ER-ADM-19.01).

Software Validation

Computer models shall be validated to demonstrate that they are, as embodied in computer software, correct representations of the process or system for which they are intended. Model demonstrations are commonly achieved by comparing data produced by the model with data taken from the real-world process or system. Specific sets of data used in the validation process shall be identified, and justification shall be made for their use. Acceptable alternative approaches to model validation include peer review and comparisons with the results of similar analyses performed with other validated models and verified software.

6.2.5 Software Configuration Control

Configuration Identification

A configuration baseline shall be defined at the completion of the software development. Changes or revisions to this baseline shall be identified and shall be developed, verified, and validated in the same manner as the original version. Approved changes or revisions created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration. The ERM software configuration control program is described in 2-G24-ER-ADM-19.01.

94-DME-ERM-027

Configuration Change Control

Computer software shall be controlled to ensure that changes are documented and approved by authorized personnel and that the software is released only to authorized users (see 2-G24-ER-ADM-19.01). When changes to previously verified computer software are made or the hardware processing environment has changed (e.g., computer codes and reconfiguration of the hardware components that directly affect software performance or

94-DME-ERM-027

computer failure), verification shall be required for the change, including evaluation of the effects of these changes.

94-DME-ERM-0127

6.2.6 Software Documentation

Software documentation shall be maintained as a QA record according to the requirements of Section 4.2, QA Records, of this QAPD. Such documentation shall include as specified:

- Software requirements
- Software design
- Software change control/revision releases
- Software test plans and results
- User's Manual, Training Guide, and User Training Rosters.

94-DME-ERM-0127

6.2.7 Software Application Control

Application control (the control of how an application is run) shall be implemented for software runs performed to generate or process data to develop conclusions that are to be reported to regulatory agencies. The requirements for software application control will be contained in written procedures which will be developed by the end function responsible for performing the analysis prior to the application's use. The purpose is to ensure that configuration-managed software is applied under the conditions specified in verification and validation documents.